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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,692	11/09/2005	Avigdor Scherz	SCHERZ4	8697

1444 7590 09/24/2009

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EXAMINER	
WARD, PAUL V	

ART UNIT	PAPER NUMBER
1624	

MAIL DATE	DELIVERY MODE
09/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,692	SCHERZ ET AL.	
	Examiner	Art Unit	
	PAUL V. WARD	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29 and 36-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29 and 36-50* is/are rejected.

7)☒ Claim(s) *4,5,8 and 9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/9/05,5/13/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II in the reply filed on June 18, 2009 is acknowledged, and found persuasive. The restriction requirement dated March 19, 2009 is hereby withdrawn.

An action on the merits on claims 1-29 and 36-50 is contained herein.

Information Disclosure Statement

Receipt of the information disclosure statements filed November 9, 2005, and May 13, 2005 is acknowledged, and copies are enclosed herewith.

Priority

Applicant is advised of possible benefits under 35 U.S.C. 119(a)-(d), wherein an application for patent filed in the United States may be entitled to the benefit of the filing date of a prior application filed in a foreign country.

A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the

application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or

an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Claim Objections

Claims 4-5 and 8-9 are objected to because of the following informalities: claims 4-5 and 8-9 is objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The issues concerning the meaning of "bacteriochlorophyll derivative" fail to comply with the written description requirement. Claim 1 does not contain a generic formula indicating structural makeup for Applicant's invention.

According to the MPEP § 2163, "a question as to whether a specification provides an adequate written description may arise in the context of an original claim which is not described sufficiently (see, e.g., LizardTech, Inc. v. Earth Resource Mapping, Inc., 424 F.3d 1336, 1345, 76USPQ2d 1724, 1733 (Fed. Cir. 2005); Enzo Biochem, 323 F.3d at 968, 63 USPQ2dat 1616 (Fed. Cir. 2002); Eli Lilly, 119 F.3d 1559, 43 USPQ2d 1398), a new or amended claim wherein a claim limitation has been added or removed, or a claim to entitlement of an earlier priority date or effective filing date under 35 U.S.C. 119, 120, or 365(c). Most typically, the issue will arise in the context of determining whether new or amended claims are supported by the description of the invention in the application as filed (see, e.g., In re Wright, 866 F.2d 422, 9 USPQ2d 1649 (Fed. Cir. 1989)), whether a claimed invention is entitled to the benefit of an earlier priority date or effective filing date under 35 U.S.C. 119, 120, or 365(c) (see, e.g., New Railhead Mfg. L.L.C. v.Vermeer Mfg. Co., 298 F.3d 1290, 63 USPQ2d 1843 (Fed. Cir. 2002); Tronzo v. Biomet, Inc., 156 F.3d 1154, 47 USPQ2d 1829 (Fed. Cir. 1998); Fiers v. Revel, 984 F.2d 1164, 25 USPQ2d 1601 (Fed. Cir. 1993); In re Ziegler, 992 F.2d 1197, 1200, 26 USPQ2d 1600, 1603 (Fed. Cir. 1993)), or whether a specification provides support for a claim corresponding to a count in an interference (see, e.g., Fields v. Conover, 443 F.2d

1386, 170 USPQ 276 (CCPA 1971)). Compliance with the written description requirement is a question of fact, which must be resolved on a case-by-case basis. Vas-Cath, Inc. v. Mahurkar, 935 F.2d at 1563, 19 USPQ2d at 1116 (Fed. Cir. 1991). There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. In re Wertheim, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976) ("we are of the opinion that the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims"). However, as discussed in paragraph I., supra, the issue of a lack of adequate written description may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention. The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art. For example, consider the claim "A gene comprising SEQ ID NO:1." A determination of what the claim as a whole covers may result in a conclusion that specific structures such as a promoter, a coding region, or other elements are included. Although all genes encompassed by this claim share the characteristic of comprising SEQ ID NO:1, there may be insufficient description of those specific structures (e.g., promoters, enhancers, coding regions, and other regulatory elements) which are also included. The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a

method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. For example, even though a genetic code table would correlate a known amino acid sequence with a genus of coding nucleic acids, the same table cannot predict the native, naturally occurring nucleic acid sequence of a naturally occurring mRNA or its corresponding cDNA. Cf. In re Bell, 991 F.2d 781, 26 USPQ2d 1529 (Fed. Cir. 1993), and In re Deuel, 51 F.3d 1552, 34 USPQ2d 1210 (Fed. Cir. 1995) (holding that a process could not render the product of that process obvious under 35 U.S.C. 103). The Federal Circuit has pointed out that under United States law, a description that does not render a claimed invention obvious cannot sufficiently describe the invention for the purposes of the written description requirement of 35 U.S.C. 112. Eli Lilly, 119 F.3d at 1567, 43 USPQ2d at 1405. Compare Fonar Corp. v. General Electric Co., 107 F.3d 1543, 1549, 41 USPQ2d 1801, 1805 (Fed. Cir. 1997) ("As a general rule, where software constitutes part of a best mode of carrying out an invention, description of such a best mode is satisfied by a disclosure of the functions of the software. This is because, normally, writing code for such software is within the skill of the art, not requiring undue experimentation, once its functions have been disclosed. * * * Thus,

flow charts or source code listings are not a requirement for adequately disclosing the functions of software.").

A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species); In re Ruschig, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967) ("If n-propylamine had been used in making the compound instead of n-butylamine, the compound of claim 13 would have resulted. Appellants submit to us, as they did to the board, an imaginary specific example patterned on specific example 6 by which the above butyl compound is made so that we can see what a simple change would have resulted in a specific supporting disclosure being present in the present specification. The trouble is that there is no such disclosure, easy though it is to imagine it.") (emphasis in original); Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1328, 56 USPQ2d 1481, 1487 (Fed. Cir. 2000) ("the specification does not clearly disclose to the skilled artisan that the inventors ... considered the ratio... to be part of their invention .... There is therefore no force to Purdue's argument that the written description requirement was satisfied because the disclosure revealed a broad invention from which the [later-filed] claims carved out a patentable portion")."

Applicants are reminded of what the U.S. Court of Appeals Federal Circuit wrote in University of California v. Eli Lilly and Co. 43 USPQ2d 1398, "[I]n claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. According, such a formula is normally an adequate description of the claimed genus." "A definition by function, as we have previously indicated, doesn't not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See Fiers, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing Amgen)." It is only a definition of a useful result rather than a definition of what achieves that result." "The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.")".

2. Claim 42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific compounds disclosed in the specification, does not reasonably provide enablement for **esters** as an intermediate of those compounds and composition containing the same. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 42 and the claims dependent thereon are rejected because claim 42 recite specific compounds and esters of said compounds. However, the specification fails to teach the preparation or identity of esters. Therefore, the specification is not adequately enabled for making and/or using esters.

Identifying an ester requires knowledge of *in vivo* regeneration pathways of instant compounds and short of extensive experimentation, would be the skilled artisan would need much more data to determine esters of the instant compounds and compositions.

Applicants have not provided any clear guidance that would provide esters of the instant compounds that will regenerate *in vivo* to the instant compounds by one or more biological processes or methods for preparing esters. It is not the norm that one can predict with any accuracy whether a particular ester form of an active compound will be more soluble, more easily handled in formulations or more bioavailable without art recognized data to support same. The specification provides no guidance as to what type(s) of esters are suitable for the instant compounds. Generally, esters themselves are not considered to be therapeutically active but only to provide the active compound *in vivo*.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

1) Nature of invention.
2) State of prior art.
3) Quantity of experimentation needed
4) Level of predictability in the art.
5) Amount of direction and guidance provided by the inventor.
6) Existence of working examples.

7) Breadth of claims.
8) Level of ordinary skill in the art.

Nature of the invention

The nature of the invention is the preparation of compounds and compositions under the genus of structural formula (II). As stated, however, esters are also intended. The nature of esters is not set forth nor is the manner in which the esters are to be prepared or the core compounds modified into esters.

State of the prior art

The state of the prior art is that esters are known in the pharmaceutical industry. Esters in related compounds are not modified.

Quantity of experimentation needed

The quantity of experimentation needed is undue. The skilled artisan would need to regenerate in vivo the instant compounds by one or more biological processes. All of which require undue experimentation. Applicant has not postulated a metabolic pathway or mechanism, which facilitate conversion of the esters into an active agent.

Level of predictability in the art

The art pertaining to the preparation and use of esters is high as esters are compound specific and not all esters have the ability to regenerate *in vivo*. (See "Wolff, M.E., "Burger's Medicinal Chemistry", pp. 975-977, and Banker et al., "Modern Pharmaceuticals", p. 596).

Amount of direction and guidance provided by the inventor

There is no guidance provided as all the examples in the specification are drawn to the preparation of compounds disclosed in the specification and not to esters. The lack of guidance to prepare any esters is not provided by the inventor.

Existence of working examples

As discussed above, working examples are drawn to the preparation of compounds disclosed in the specification and not to esters. The lack of guidance to prepare any esters is telling. There is no direction or guidance provided by Applicant to prepare esters of the instant invention.

Breadth of claims

The breath of the recited compounds and compositions in the claims includes esters for which there have been provided no specific examples or procedural steps to prepare esters. Failure to teach how to make the instant compounds makes teaching how to use the compounds unduly difficult, if not impossible.

Level of ordinary skill in the art

The level of ordinary skill in the art is high due to the unpredictability in the chemical art.

Hence, as discussed above, to practice the claimed invention herein, a person of ordinary skill in the art would have to engage in undue experimentation to test which ester can be used in the instant claim, with no assurance of success. Therefore, applicant must show that the specification teach the preparation of esters, or limit the claims accordingly.

3. Claims 20-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention without undue experimentation.

Claims 20-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim is directed to a pharmaceutical composition or compositions comprising the claimed compounds. The claims are rejected for lack of enablement because there is an insufficient teaching of how to use the claimed compositions as claimed. The term "pharmaceutical composition" specifies that at least some therapeutic benefit arise from some property of the composition. Intended use claims do not have patentability weight. A pill, for example, is a pill no matter what it is used for, and thus, intended use are not considered patentable. Therefore, Applicant has not taught how to use the compounds of the invention to therapeutic effect for any condition.

Examiner suggests amending a claim to read "A pharmaceutical composition containing at least one compound of claim 1, or a pharmaceutically acceptable salt thereof."

4. Claims 36, 38 and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention without undue experimentation.

Claims 36, 38 and 40 are directed to a method of treating and diagnosing a tumor. The term tumor is interpreted to include any and all forms of tumors. In light of this, it can be asserted that in spite of the vast expenditure of human and capital resources in recent years, no one drug has been found which is effective in treating all

types of tumors because it is not a simple disease, nor is it even a single disease, but a complex of a multitude of different entities, each behaving in a different way. In re Hozumi, 226 USPQ 353 (ComrPats 1985).

The determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations. In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include, but are not limited to:

(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims

The breadth of the instant claim is seen to encompass methods for treating tumors by administering to a patient in need of such treatment a therapeutically effective amount of a bacteriochlorophyll compound of claim 1. Applicants failed to exactly define what types of tumors are treated. Thus, the claims are extremely broad.

The scope of use that Applicants intend to claim is also very broad. To this day, it is impossible to treat all tumors with a single pharmaceutical drug. The term, "tumor", covers more than just cancers. It also covers many neoplasms, cancerous or not. A neoplasm is any abnormal tissue that grows by cellular proliferation more rapidly than normal, or continues to grow after the stimulus that initiated the new growth has ceased, or shows lack (partial or complete) of structural organization and/or coordination with surrounding tissue. It can be benign or malignant. Thus, such a term, also covers precancerous conditions such as lumps, lesions, and polyps. In addition, "tumor" covers things other than neoplasms. It also covers any kind of swelling arising from inflammation. Thus, the claim would cover treatment of many kinds of inflammation, and this is not supported by specification.

The nature of the invention

The nature of the invention is the treatment of tumors through the use of the claimed compound and derivatives thereof. Currently, there are no known agents that treat tumors all inclusively. (See Pinedo et al. pages 1-2). Additionally, the claim sets forth the treatment of tumors generally. However, there never has been a compound capable of treating tumors generally. There are compounds that treat a range of tumors, but no one has ever been able to figure out how to get a compound to be effective against tumors generally, or even a majority of tumors. Thus, the existence of such a "silver bullet" is contrary to our present understanding in tumor science or oncology. Even the most broadly effective antitumor agents are only effective against a small fraction of the vast number of different tumors or cancers known. This is true in

part because cancer can arise from a wide variety of sources, such as viruses (e.g. EBV, HHV-8, and HTLV-1), exposure to chemicals such as tobacco tars, genetic disorders, ionizing radiation, and a wide variety of failures of the body's cell growth regulatory mechanisms. Different types of cancers affect different organs and have different methods of growth and harm to the body, and different vulnerabilities. Thus, it is beyond the skill of oncologists today to get an agent to be effective against cancers generally, evidence that the level of skill in this art is low relative to the difficulty of such a task.

The level of predictability in the art

The treatment of tumors is highly unpredictable due to the differing forms, their location, their potential for metastases, and the fact that tumor therapeutics is palliative rather than curative and that tumor treatment readily harms normal tissues. (See McMahon, page 5, col. 2). The term, "tumor", covers more than just cancers. It also covers many neoplasms, cancerous or not. A neoplasm is any abnormal tissue that grows by cellular proliferation more rapidly than normal, or continues to grow after the stimulus that initiated the new growth has ceased, or shows lack (partial or complete) of structural organization and/or coordination with surrounding tissue. It can be benign or malignant. Thus, such a term, also covers precancerous conditions such as lumps, lesions, and polyps. In addition, "tumor" covers things other than neoplasms. It also covers any kind of swelling arising from inflammation. Thus, the claim would cover treatment of many kinds of inflammation, and this is not supported by specification.

The amount of direction provided by the inventor.

The applicant has not demonstrated sufficient guidance provided in the form of administration profiles, combination ratios of the active agents or reference to the same in the prior art to provide a skilled artisan with sufficient guidance to practice the instant treatment of tumors claimed. Further, the applicant discloses that an effective amount of the compound will be administered without providing any direction other than that the compounds of the invention have a high therapeutic index and follows this with a definition readily found in a basic pharmacology textbook. It should be noted that the therapeutic index of a drug in humans is almost never known and is only determined through clinical experience.

The existence of working examples.

There is not seen in the disclosure, sufficient evidence to support Applicant's claims of treating solid tumors. A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 27 USPQ2d 1510 (CAFC). The disclosure does not demonstrate sufficient evidence to support the applicant's claim to the treatment of tumors. There are not sufficient working examples or data from references of the prior art to provide a nexus between those examples and a method of treating tumors with the claimed compound.

The level of one of ordinary skill.

The level of skill is that of one with a doctoral understanding of tumor and cancer therapeutics.

The quantity of experimentation.

A great deal of experimentation is required. In order for there to be a method of treating tumors generally, as claimed by the applicant, it would be necessary to show that a vast range of different types of tumors that can be treated that have differing cell types, locations and potentials for metastases. Furthermore, direction, in the form of examples, must be shown to determine what an effective dose may be. The references submitted do not demonstrate this. Therefore, one of ordinary skill in the art would require a significant amount of experimentation in order to determine the effective dosage to treat the multitudes of different types of tumors with the claimed compound individually or in combination with other therapeutic agents.

Thus, it can be safely concluded that the instant case fails to provide an enabling disclosure for the treatment and diagnoses of tumors.

5. Claims 36-37 and are directed to a method of treating tumors (as discussed supra) and age-related macular degeneration. The terms are interpreted to include any and all forms of treating tumors and age-related macular degeneration. In light of this, it can be asserted that in spite of the vast expenditure of human and capital resources in recent years, no one drug has been found which is effective in treating all types of treating tumors and age-related macular degeneration. In re Hokum, 226 USPQ 353 (ComrPats 1985).

The determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual determination.

Rather, it is a conclusion reached by weighing all the above noted factual considerations. In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include, but are not limited to:

(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims

The breadth of the instant claims is seen to encompass methods for treating tumors and age-related macular degeneration by administering to a patient in need of such treatment a therapeutically effective amount of the compound claim. Applicant failed to exactly define what types of treating tumors and age-related macular degeneration are treated. Thus, the claims are extremely broad.

The nature of the invention

The nature of the invention is the treatment of treating tumors and age-related macular degeneration through the use of the claimed compound and derivatives thereof. Currently, there are no known agents that treat these diseases all inclusively.

The level of predictability in the art

The treatment of treating tumors and age-related macular degeneration is highly unpredictable. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and physiological activity is generally considered to be an unpredictable factor. See In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

The amount of direction provided by the inventor.

The applicant has not demonstrated sufficient guidance provided in the form of administration profiles, combination ratios of the active agents or reference to the same in the prior art to provide a skilled artisan with sufficient guidance to practice the instant treatment of treating tumors and age-related macular degeneration disorders claimed. Further, the applicant discloses that an effective amount of the compound will be administered without providing any direction other than that the compounds of the invention have a high therapeutic index and follows this with a definition readily found in a basic pharmacology textbook. It should be noted that the therapeutic index of a drug in humans is almost never known and is only determined through clinical experience.

The existence of working examples.

There is not seen in the disclosure, sufficient evidence to support Applicant's claims of treating tumors and age-related macular degeneration disorders. A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 27 USPQ2d 1510 (CAFC). The disclosure does not demonstrate sufficient evidence to support the applicant's claim to the treatment. There are not sufficient working examples or data from references of the prior art to provide a nexus between those examples and a method of treating tumors and age-related macular degeneration disorders with the claimed compound.

The level of one of ordinary skill.

The level of skill is that of one with a doctoral understanding of treating tumors and age-related macular degeneration disorders therapeutics. Applicant's data is not convincing as to make the production and use of pharmaceutical compositions comprising the recited compounds feasible without undue, un-predictable experimentation.

The quantity of experimentation.

A great deal of experimentation is required. In order for there to be a method of treating tumors and age-related macular degeneration disorders generally, as claimed by the applicant, it would be necessary to show that a vast range of different types of treating tumors and age-related macular degeneration disorders. Furthermore, direction, in the form of examples, must be shown to determine what an effective dose may be.

The references submitted do not demonstrate this. Therefore, one of ordinary skill in the art would require a significant amount of experimentation in order to determine the effective dosage to treat the multitudes of different types of treating tumors and age-related macular degeneration diseases with the claimed compound individually or in combination with other therapeutic agents.

Thus, it can be safely concluded that the instant case fails to provide an enabling disclosure for the treatment of treating tumors and age-related macular degeneration disorders.

6. Claims 39 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement because the specification does not enable the improvement of for photodynamic therapy using a photosynsitizer for methods for killing of cells or infectious agents, using a therapeutically effective amount of a compound corresponding of formulae I and II and claim 1 or enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

Claims 39 and 41 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Improving photodynamic therapy is critical or essential to the practice of the invention, but is not included in the claims, and thus, is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

The how to use portion of the statute has not been addressed. This means that Applicants must teach the skilled practitioner, in this case an individual with a doctoral understanding with bacteriochlorophyll and microbiology, how to treat a given subject.

The skilled artisan clearly must know what disease and what symptoms are to be treated. In this case, Applicants have not provided what is being treated by claims 39 and 41, the subject, how one can identify said subject (i.e. how one can identify a subject in need), given no specific dose, given no specific dosing regimen, given no specific route of administration, and do not specify what diseases or symptom they intend to treat.

Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. Tossing out the mere germ of an idea does not constitute enabling disclosure. Genentech Inc. v. Novo Nordisk 42 USPQ2d 1001.

As the Supreme Court said in *Brenner v. Manson*, 148 USPQ at 696: "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." As U.S. Court of Customs and Patent Appeals stated *In re Diedrich* 138 USPQ at 130, quoting with approval from the decision of the board: "We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates."

This claims, for example, would read on all photodynamic therapy employing a photosensitizer as a bacteriochlorophyll. The specification fails to teach any benefit to be gained from such actions. Is extensive experimentation required on the part of a potential infringer to determine if their use of Applicants' compound falls within the limitations of Applicants' claim? *In re Kirk and Petrow*, 153 USPQ 48 (CCPA 1967).

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-17, 19-29 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claim 1 and claims dependent thereon, sets forth the term "derivative". In the absence of the specific derivatizations to the chemical core claimed or distinct language to describe the structural modifications or the chemical names of derivatized chemical core claimed of this invention, the identity of said derivatives would be difficult to describe and the metes and bounds of said derivatives applicants regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims. Additionally, the term "derivative", implies more than what is being positively recited. The term "derivative" can include any or all organic compounds derived from the core structure, and thus, it is unclear what is included or excluded. Examiner suggests replacing the term "derivative" with "compound".

(b) Claims 42 is indefinite because the claims recite the phrase "ester sodium salt, as an intermediate". It is not clear intended by the term "intermediate"? Is it the intermediate used to prepare the bacteriopheophorbide itself? In which case the structural make-up of the product salt of the intermediate and intermediate remain unknown? In addition, as recited it appears that the process is for making a mixture of a salt of bacteriopheophorbide and undefined intermediate.

(c) Claims 1 and 6 and claims dependent thereon are indefinite as it recites negatively charged groups, acidic groups, natural or synthetic derivative. The terms are relative terms, which renders the claim indefinite. The terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

(d) Claims 7 and claims dependent thereon are indefinite for reciting heteroatoms and heterocyclic moieties. The terms are indefinite since the specification does not define the ring size, heteroatom, number and nature of substituents, and the exact point of contact with the atom(s) for the substituents. Correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-18 and are rejected under 35 U.S.C. 102(b) as being anticipated by Scherz et al. (U.S. Patent 6,147,195).

Applicant teaches bacteriochlorophyll compounds wherein all the variables are as defined in the claims.

Scherz discloses bacteriochlorophyll compounds, which share the same formulaic compounds. (See Abstract and figures 1-5). The compounds in the said patent reads on the instant claim. (See figures 1-5, col. 3-4 and examples 1-17). Since Scherz teaches the exact compounds, Applicant's claims are anticipated, and thus, rejected under 35 U.S.C. 102(b).

9. Claims 43-50 and are rejected under 35 U.S.C. 102(b) as being anticipated by Scherz et al. (U.S. Patent 5,955,585).

Applicant teaches methods of preparing bacteriochlorophyll compounds wherein all the variables are as defined in the claims.

Scherz discloses methods of preparing bacteriochlorophyll compounds. (See Abstract and figures 1-5). The methods of preparing bacteriochlorophyll compounds in the said patent reads on the instant claim. (See figures 4-5, col. 9-20 7). Since Scherz teaches the exact methods of preparing, Applicant's claims are anticipated, and thus, rejected under 35 U.S.C. 102(b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-18 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scherz et al. (U.S. Patent 6,147,195).

Scherz teaches a generic group of bacteriochlorophyll derivatives, which embraces Applicants' claimed compounds. (See formula 1, col. 3 and definitions for Y, A, R, X, R). The claims differ from the reference by reciting specific species and a more limited genus than the reference. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties, and thus, the same use as taught for the genus as a whole. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. A prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus. Thus, Applicant's claims are obvious, and therefore, rejected under 35 U.S.C. 103.

Conclusion

Claims 1-29 and 36-50 are pending. Claims 1-29 and 36-50 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL V WARD whose telephone number is 571-272-2909. The examiner can normally be reached on M-F 8 am to 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/PAUL V WARD/
Examiner, Art Unit 1624